



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 10 1999

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Scott G. Beach
8185 Walnut Fair Circle
Fair Oaks, CA 95628-2743

Re: Docket No. 99P-1149/CP1

Dear Mr. Beach:

This is in response to your citizen petition, dated April 19, 1999, requesting that the "WARNINGS" section of the labeling of Mintezol contain the following statement: "Mintezol use may cause threadworms (*Strongyloides stercoralis*) to migrate out of the user's body, thereby increasing the risk that the infection may be transmitted to other people."

In support of your request, you recounted an experience in 1990 when you took Mintezol tablets for three days and infective threadworm larvae exited your body. You also cited an article in the July 1994 issue of *Discover* magazine in which Dr. Tony Dajer stated that threadworm larvae can "be spread from feces to hands or sheets and then to other people." In addition, you cited an article published in 1995 in *Parasitology* in which the authors reported that the prevalence of threadworm infection "was highest among persons who shared a bedroom with a reference case," and that this pattern of infection "is indicative of close contact transmission."

You contend that the current labeling for Mintezol does not clearly state that if a person ingests Mintezol, threadworms may migrate out of his or her body. Nor does the labeling warn Mintezol users that such migration exposes other people to the risk of threadworm infection by "close contact transmission."

FDA is sympathetic to the experience you described, and we appreciate your interest in appropriate drug product labeling. However, based on the information submitted in support of your petition, the Agency denies your request.

You stated that you observed threadworms (*Strongyloides stercoralis*) migrating out of your body. However, *Strongyloides stercoralis* larvae are not visible to the naked eye. Thus, it does not seem that your experience could be explained by *Strongyloides* infection.

One helminth (worm) that infects the gastrointestinal tract and is visible to the naked eye is *Ascaris lumbricoides*. Although a diagnosis is not possible based on your written account alone, it is possible that you were also infected with *Ascaris lumbricoides* (although *Ascaris* is usually noted to be a single adult worm when visualized by infected patients). The life cycle of *Ascaris lumbricoides* does not include an auto-infection phenomenon.

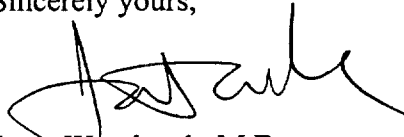
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The current labeling of Mintezol includes the following statement: "Mintezol is not suitable for the treatment of mixed infections with ascaris because it may cause these worms to migrate." It is possible that you were also infected with *Ascaris*, in which case the events you observed are already addressed in the current labeling of Mintezol.

For the reasons stated above, FDA denies your petition. Do not hesitate to contact me if I can be of any further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Janet Woodcock', written over a horizontal line.

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research